REMARKS

Claims 1-3, 5-7, 9-13, 15-18, 20-28 and 52-55 are now pending in the application with claims 4, 8, 14, and 19 having been cancelled herein. Numerous grounds of objection and rejection were applied to the application in the office action, each of which is addressed below.

Objection to the Specification

The examiner has objected to the previous amendment which added Fig. 30 as introducing new matter into the disclosure. In a previous office action, the examiner objected to the drawings under 37 CFR 1.83(a) in view of the then pending claims. Applicant therefore submitted a proposed new Fig. 30 illustrating the steps of correcting a flow resistance based upon a ratio of a measured flow and a calculated flow along with a corresponding amendment of the specification to describe the figure. Fig. 30 merely enumerates specific steps described elsewhere in the specification, such as in the paragraph starting at line 13 on page 57. Applicant therefore asserts that the new Fig. 30 and corresponding amendment were substantially disclosed in the specification as filed and therefore do not constitute new matter.

Claim for Priority

Applicant believes the claims as amended herein are entitled to an effective filing date of February 3, 1998 based upon provisional application 60/073,580 to which applicant claims priority.

Rejections Under 35 U.S.C. § 103

Claims 1-4, 10-14, 20, and 22-24 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al., or Kamm et al., in view of any of Clark et al. (1989, pp. 217-230), Himwich et al. (1965, pp. 164-172), or Himwich et al. (1974). Claims 5-7 and 25-28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al., or Kamm et al., in view of any of Clark et al. (1989, pp. 217-230), Himwich et al. (1965, pp. 164-172), or Himwich et al. (1974), and further in view of Karplus or Foutrakis. Applicant has amended the claims herein and asserted those claims to have an effective filing date of February 3, 1998.

Applicant therefore requests removal of Kamm (U.S. Patent No. 6,117,087) with its filing date of April 1, 1998 as a prior art reference under section 102(e). The rejections based upon Kamm as applied to the claims before this amendment are respectfully traversed for the record, however, and applicant reserves the right to prosecute claims reciting the same or similar subject matter in this or a subsequent application.

With respect to the claims as presently amended, applicant does not believe the prior art references cited in the office action constitute a *prima facie* case of obviousness under section 103. Independent claims 1, 12, and 23 recite a method, apparatus, and system, respectively, recite subject matter similar to the following: 1) a patient's arterial system is simulated by a computer model which includes a plurality of arterial segments, 2) the model is adapted to the patient's individual anatomy, 3) a blood flow in a selected arterial segment is calculated by the model, 4) a blood flow corresponding to the calculated blood flow is measured in the patient, 5) the computer model is corrected based upon the measured and calculated blood flows, 6) the computer model is modified to simulate a particular surgical reconstruction, and 7) the modified model calculates a post-operative blood flow in a selected arterial segment in order to predict an outcome of the actual surgical reconstruction performed in the patient. Applicant does not believe that the combination of the Charbel et al, Clark, and Himwich references teaches or suggests this subject matter. The Charbel 1996 presentation abstract describes a clinical study in which a computerized model of the cerebral circulation was used to simulate the circulation of 82 patients who underwent a surgical reconstruction. Direct blood flow measurements were performed during the surgeries both before and after the reconstruction, and corresponding blood flows were calculated by the model. Across the 82 patients, there was found to be a linear correlation between the measured blood flows and those predicted by the model, both before and after the surgical reconstruction. This was asserted in the presentation to be evidence of the validity of the computer model. No teaching or suggestion is put forth, however, for correcting the model in a patient-specific manner based upon a measured flow in an individual patient. The examiner's statement to the effect that the presentation abstract describes the performance of a "remodeling" procedure to correct for any discrepancies observed between predicted and actual values is simply incorrect. In the clinical study, predicted blood flows (i.e., as calculated by the

model) in the different patients were found to be correlated with the measured blood flows in the same patients but were not used to correct the computer model. As stated previously, the phrase "vascular remodeling procedures" as used in the presentation abstract refers to surgical reconstructive procedures, and not to a correction of the computer model to account for differences between predicted and measured flows. As evidence of this use of the term "remodeling," applicant submits herewith, as Exhibit A, a copy of the first page of a journal article entitled "Laparoscopic remodeling of abdominal aortic aneurysms after endovascular exclusion: A technical description," cited as J Vasc Surg 2002;36:1267-70. Thus, fairly read, the Charbel et al. references do not teach the correction of a circulatory system model in a patient specific manner based upon measured blood flow. The Clark et al. and Himwich et al. references also do not teach or suggest modifying a circulatory system model in a patient-specific manner. The adjustment of vessel resistances described in those references was not for the purpose of constructing a patient-specific model in order to predict the outcome of a surgical reconstruction. Instead, the resistance adjustments were performed so that the model would simply calculate flows that were in a physiological range.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP 2143.03; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As none of the prior art references of record teach or suggest the correction of a computerized circulatory system model in a patient-specific manner based upon a flow measurement and using that model to predict an outcome of a surgical operation, applicant does not believe that a *prima facie* case of obviousness has been made with respect to claims 1, 12, and 23. The recitations of dependent claims 2, 3, 5-7, 9-11, 13, 15-18, 20-22, 24-28, and 52-55 are further limitations to the patentable subject matter recited by either claim 1, 12, or 23 and are neither taught nor suggested by the prior art of record in that context. Applicant therefore believes all of the pending claims are allowable over the prior art of record.

CONCLUSION

In view of the foregoing amendments and remarks, applicant believes that application is in condition for allowance and respectfully requests such action. Please charge any fees deemed necessary to Deposit Account 19-0743. The examiner is invited to telephone applicant's attorney, J. Kevin Parker, Reg. No. 33,024, at 847-432-7302 to discuss any questions that may remain with respect to the present application.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner of Patents, Washington, D.C. 20231 on **January 5, 2004**.

Name Tina Kohut

Signature _____

Exhibit A

TECHNICAL NOTE

Laparoscopic remodeling of abdominal aortic aneurysms after endovascular exclusion: A technical description

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We report our experience with a novel combined laparoscopic–endovascular procedure to treat endoleaks and graft migration. The operative procedure consisted of the following steps: laparoscopic exposure of the aorta, clipping of lumbar arteries and of the inferior mesenteric artery, incision of the sac of the aneurysm without clamping the aorta, and removal of thrombus material. Laparoscopic sutures were placed externally to attach the endograft to the aortic neck. Laparoscopy was performed a mean interval of 20.2 months after endovascular abdominal aortic aneurysm repair in four cases and immediately after endovascular abdominal aortic aneurysm exclusion in eight consecutive patients. We have yet to prove whether this combined approach is superior to a purely endovascular technique. (J Vasc Surg 2002;36: 1267-70.)

Endoleaks are conditions associated with endoluminal vascular grafts placed for the treatment of aneurysms defined by the presence of blood flow outside the lumen of the endoluminal graft into the sac of the aneurysm.[1] With concentration on type II endoleaks only, the problems of device migration and the presence of the intraluminal thrombus are neglected.[2] Thrombus is a self-sustaining entity with cellular penetration that further weakens the aortic wall.[3] Therefore, we tried to develop a technique that addresses the problem of patent inflow vessels, thrombus formation, and graft migration. We report our preliminary experience with a novel hybrid procedure that attempts to combine endovascular with videoendoscopic techniques.

MATERIAL AND METHODS

Informed consent was obtained in all cases with explanation to the patient of the experimental nature of this hybrid approach. The laparoscopic part of the operation consisted of the following steps: clipping of lumbar arteries, transsection of the inferior mesenteric artery, incision of the sac of the aneurysm, removal of thrombus material, and laparoscopic closure of the sac of the aneurysm. Interrupted sutures were used to accomplish fixation of the endograft to the aortic neck. All patients underwent transfemoral angiography and delayed contrast spiral scan.

Computed tomographic scan before the operative procedure. We used the left retrocolic approach originally described in recent publications by Dion and Gracia[4] and Dion, Gracia, and Ben El Kadi[5] because this permitted easier access to the lumbar arteries. If we could not succeed totally laparoscopically, hand assisted laparoscopy was used with a hand port device to try to avoid conversion to a conventional laparotomy.[6,7]

Operative technique. In the first series, laparoscopy was offered to patients with an increase of the diameter of the aneurysm after endovascular abdominal aortic aneurysm (AAA) repair. In a second consecutive series of patients, laparoscopy was performed as an adjunctive procedure immediately after insertion of the stent graft to avoid technical problems related to the retroperitoneal inflammatory reaction after previous endoluminal AAA repair.

The aorta was exposed with the transabdominal, left retrocolic access recently described in detail by Dion and Gracia[4] as the "apron" technique (Fig 1). The inferior mesenteric artery was identified and transsected. As many lumbar arteries as were accessible were clipped and transsected first on the left side of the aorta. Subsequently, we tried to elevate the aorta to identify and clip from underneath the lumbar arteries on the right side.

For safety reasons, a laparoscopic aortic clamp was inserted through a stab incision and placed adjacent to the neck of the aneurysm yet not occluded. Without clamping of the aorta, the sac of the aneurysm was incised over a

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Competition of interest: nil.
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